STATE OF MISSOURI

REVISED GENERIC DRUG FORMULARY

GENERIC DRUG NEGATIVE FORMULARY
AUGUST 2004 UPDATE (REVISED 8/12/04)

IMPORTANT INFORMATION

In certain instances, the same drug may be listed two or more times in order to identify drug manufacturers that are considered bioequivalent to each other within a specific group. When this occurs, each group will be noted as such with the number to note it as one of two or more groups of drug manufacturers. **While each manufacturer in a particular group is bioequivalent to the other manufacturers listed in a group, one group will not be considered bioequivalent to another group. Only manufacturers within the same group can be interchanged for drug substitution purposes.**

SYNOPSIS OF GENERIC SUBSTITUTION IN MISSOURI

Missouri law provides that all prescription forms have two signature lines at the bottom of the form. Under the line appearing in the lower left corner of the form shall appear the words **"Substitution Permitted"**. Under the line appearing in the lower right corner of the form shall appear the words, **"Dispense as Written"**. By signing the prescription form on the left, above the line marked **"Substitution Permitted"**, the prescriber allows the pharmacist to substitute a less expensive drug product in the place of the drug product prescribed, within the parameters of the Negative Formulary. No prescription that originates within the state of Missouri shall be valid unless it complies with this form and is signed by the prescriber on one of these lines. When an oral, facsimile, or electronic prescription is involved, specific instructions must be provided to and recorded by the pharmacist regarding permission to engage in substitution.

The use of the Negative Formulary is very simple. In general, when a compound is listed in the Negative Formulary, substitution is **prohibited.** However, in the case of certain compounds the names of specific manufacturers are listed immediately adjacent to those compounds. This indicates that although the compound listed is generally prohibited from substitution, the drug products available from the listed manufacturers are permitted for substitution.

Approved Prescription Drug Products

This term refers to currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of section 505, or in the case of antibiotics, through analogous applications known as Forms 5 or 6 under section 507 of the Federal Food, Drug and Cosmetic Act (the Act). All drug products on the list have been fully reviewed and approved for safety and effectiveness by FDA. Also, the law permits drugs to be legally marketed without such fully approved applications under certain circumstances but the drugs so marketed do not appear on the list.
For more information regarding consideration by the N.F.R.C. or if you have questions about the formulation and utilization of the Negative Formulary, you may contact:

Missouri State Board of Pharmacy
P.O. Box 625
Jefferson City, MO 65102

MISSOURI LAW GOVERNING GENERIC DRUG SUBSTITUTION

338.056. Generic substitutions may be made, when, form required for prescription blanks - penalty.

1. Except as provided in subsection 2, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2. The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. The pharmacist shall not select a drug product pursuant to this section unless the product selected costs the patient less than the prescribed product.
2. A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:
   (1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines.
   (2) If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may be substituted. The pharmacist shall note the instruction on the file copy of the prescription.
3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with the section 2 hereof.
4. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription written by a practitioner licensed in a state other than Missouri according to the laws regarding generic substitution in such other state.
5. Violations of this section are infractions.

338.057. List of nonacceptable substitutions-preparation-publication. The department of economic development shall publish a list of drug products for which substitution as provided in section 338.056 shall not be permitted. The list of drug products to be included on this list shall be based upon a joint determination made by the department of health, the state board of registration for healing arts, and the state board of pharmacy. The Department of Economic Development shall publish the list no less often then semiannually, and shall publish amendments to the list as required.

338.196. Prescription by practitioner licensed in another state, may be filled, requirement. Notwithstanding the provisions of section 338.056 to the contrary, a pharmacist may fill a prescription

written by a practitioner licensed in a state other than Missouri according to the practitioner's direction as to generic substitution

SAMPLE PRESCRIPTION FORM

Date_____

For_____

Address_____

.....

SIG:

_____ _____

SUBSTITUTION PERMITTED **DISPENSE AS WRITTEN**

CODE OF STATE REGULATIONS

4CSR 220-3.011 GENERIC DRUG FORMULARY

PURPOSE: *The purpose of this rule is to comply with section 338.057 RSMo which directs the Department of Economic Development to publish a list of drug products for which substitution, by a pharmacist, shall not be permitted. Noting that there are a number of drug products within a specific drug product category that have been proved bioequivalent and bio-available to the Federal Food and Drug Administration, the Department of Economic Development has delineated within a particular drug product category those drugs that may be substituted. The list is dual in nature. There are certain drugs where substitution will not be permitted and there are certain drug products where qualified substitution will be allowed, again only if the drug manufacturer is specifically designated in the list.*

(1) If a written prescription is involved, the prescription form used shall have two (2) signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines.

(2) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.

(3) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of the "Approved Drug products with Therapeutic Equivalence Evaluations" published by the United States government, Department of Health and Human Services.

(4) Any drug that is manufactured by an innovator company under a supplement to their New Drug Application (NDA) for that specific drug may apply to the Missouri Board of Pharmacy for consideration as a drug that is generically equivalent to the innovator product. A written request for such consideration must be accompanied by an affidavit or other acceptable documentation from the Food and Drug Administration (FDA) attesting to the equivalency of the generic product to the innovator product. Once the Missouri Board of Pharmacy determines that the two (2) products are considered generically equivalent under state law, an appropriate notation will be made in the next revision of the Generic Drug Formulary.

Auth. Chapter 338.057, RSMo (Supp. 1986). For history of amendment, see Code of State Regulations. Amended: Filed April 17, 1989, effective September 1, 1990. Amended: Filed August 25, 1995, effective April 30, 1996.

Any portions of the list that appear with a strike through are considered deleted from the list. Any portions of the list that appear in bold type are considered new editions to the list.

PRESCRIPTION DRUG PRODUCT LIST

ALBUTEROL AEROSOL (Group 1)
- Armstrong
- GenPharm
- Glaxo Smith Kline (Ventolin)
- Ivax
- Pliva

ALBUTEROL AEROSOL (Group 2)
- Schering
- Warrick

BECLOMETHASONE DIPROPIONATE

BECLOMETHASONE DIPROPIONATE MONOHYDRATE

BUPROPRION HCL; TABLET, EXTENDED RELEASE **100MG; 150MG (Group 1)**
- **Eon**
- **Impax**
- GlaxoSmithKline (Wellbutrin)

BUPROPRION HCL; TABLET, EXTENDED RELEASE 150MG (Group 2)
- **Impax**
- **GlaxoSmithKline (Zyban)**

CHLOROTHIAZIDE; RESERPINE

CHLORPROMAZINE HCL; TABLET

CLINDAMYCIN PHOSPHATE GEL; TOPICAL
- Altana
- Pharmacia and Upjohn

CLOBETAZOLE PROPIONATE CREAM (Group 1)

Alpharma US Pharm
Copley Pharm
Fougera
Glaxo Smith Kline (Temovate)
Healthpoint (Cormax)
Stiefel
Taro

CLOBETAZOLE PROPIONATE CREAM (Group 2)
Altana
Glaxo Smith Kline (Temovate E)
Healthpoint (Embeline E)
Stiefel
Taro

CLOTRIMAZOLE CREAM; TOPICAL
Schering
Taro

COLCHICINE; PROBENECID

CORTICOTROPIN INJECTION

CORTISONE ACETATE TABLET

CYCLOSPORINE CAPSULE 25MG; 100MG (Group 1)
Abbott
Eon
Novartis (Neoral)
Pliva

CYCLOSPORINE CAPSULE 25MG; 100MG (Group 2)
Novartis (Sandimmune)
Torpharm

CYCLOSPORINE CAPSULE 50MG

CYCLOSPORINE ORAL SOLUTION 100MG/ML
Abbott
Novartis (Neoral)
Pliva

DESMOPRESSIN ACETATE SOLUTION; NASAL

DEXAMETHASONE TABLET, 0.25 MG; 1 MG; 2 MG

DEXAMETHASONE TABLET; 0.5 MG; 0.75 MG; 1.5 MG; 4 MG
MSD
Roxane

DEXAMETHASONE TABLET, 6 MG

DIFLORASONE DIACETATE CREAM; TOPICAL (Group 1)
Altana
Dermik
Taro

DIFLORAXONE DIACETATE CREAM; TOPICAL (Group 2)

Altana
Pharmacia and Upjohn (Florone E)

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 1)
Aventis (Cardizem SR)
Biovail (Brand name Tiazac not included as equivalent; Cardizem CD 360mg not Included as equivalent)
Mylan
Teva

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 2)
Andrx
Mylan
Torpharm
Watson

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 3)
Andrx (Cartia XT)
Biovail (Brand name Tiazac not included as equivalent; Cardizem CD 360mg not included as equivalent)
Purepac
Torpharm

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 4)
Andrx (Taztia XT)
Biovail (Tiazac) (Cardizem CD 360mg not included as equivalent)

DYPHLLINE

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.025MG./24 HR

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.0375MG/24 HR
Novartis

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.05MG./24 HR (Group 1)
Novartis

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.05 MG/24 HR (Group 2)
Berlex
Mylan

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.1MG./24 HR (Group 1)
Novartis (Vivelle)
Mylan

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.1MG./24 HR (Group 2)
Berlex
Mylan

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, 0.02mg; 0.1mg; ORAL-21 (Group 1)
Barr
Duramed Pharm Barr
Wyeth Ayerst

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, 0.02mg; 0.1mg; ORAL-21 (Group 2)

Barr
Berlex

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, (All Other Strengths) ORAL-21
Barr
Duramed Pharm Barr
Monarch
Watson
Wyeth Ayerst

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, 0.02mg; 0.1mg; ORAL-28
Barr
Berlex
Duramed Pharm Barr
Monarch
Watson
Wyeth Ayerst

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, ORAL-28 All Other Strengths
Barr (Lessina-28)
Berlex
Monarch
Watson

FLUNISOLIDE NASAL SPRAY; METERED
Bausch and Lomb
Ivax (Nasalide)

FLUOCINONIDE CREAM; TOPICAL (Group 1)
Alpharma U.S.
Fougera
Medicis (Lidex)
Taro
Teva

FLUOCINONIDE CREAM TOPICAL (Group 2)
Alpharma U.S.
Altana
Draxis
Medicis (Lidex E)
Taro
Teva

FLUOXYMESTERONE

FOLLITROPIN ALPHA/BETA, INJECTION

GALLIUM CITRATE (GA-67)

GLYBURIDE TABLET 1.25MG; 2.5MG; 5MG
Corepharma
Pharmacia and Upjohn
Teva

HYDROCORTISONE, TABLET

HYDROCORTISONE ACETATE; PRAMOXINE HCL, AEROSOL; TOPICAL

IBUPROFEN, SUSPENSION, ORAL
Alpharma
McNeil

IRON DEXTRAN, INJECTION

LEUCOVORIN CALCIUM TABLET, 5 MG
Barr
Par
Pharmachemie
Roxane

LEVONORGESTREL

LEVOTHYROXINE SODIUM, TABLET; ORAL **(Group 1)**
Jones Pharma
Mylan
Stevens J

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 2)
Alara
Mova
Mylan
Abbott

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 3)
Alara
Jones Pharma
Mova
Mylan
Stevens J

MEDROXPROGESTERONE ACETATE TABLET, 10 MG
Barr
Duramed
Pharms Barr
Pharmacia and Upjohn

METFORMIN HCL , EXTENDED RELEASE 500MG
Bristol Meyers
Ivax

MENOTROPINS (FSH;LH)

METHYLPHENIDATE HCL CAPSULE, EXTENDED RELEASE

METHYLTESTOSTERONE CAPSULE

METHYLTESTOSTERONE TABLET

MORPHINE SULFATE CAPSULE, EXTENDED RELEASE

MORPHINE SULFATE TABLET, EXTENDED RELEASE
AB Generics
Endo Pharm
Mallinckrodt
Purdue Frederick
Watson

MUPIROCIN OINTMENT; TOPICAL
Clay Park
GlaxoSmithKline
Teva

NIFEDIPINE, TABLET, EXTENDED RELEASE 30 MG (GROUP 1)
Bayer
Biovail
Elan

NIFEDIPINE, TABLET, EXTENDED RELEASE 30 MG (GROUP 2)
Biovail
Pfizer

NIFEDIPINE, TABLET, EXTENDED RELEASE 60MG (GROUP 1)
Bayer
Biovail
Elan

NIFEDIPINE, TABLET, EXTENDED RELEASE 60MG (GROUP 2)
Biovail
Pfizer

NIFEDIPINE, TABLET, EXTENDED RELEASE 90MG (GROUP 1)
Bayer
Biovail

NIFEDIPINE, TABLET, EXTENDED RELEASE 90MG (GROUP 2)
Martec
Pfizer

NITROGLYCERINE FILM, EXTENDED RELEASE; TRANSDERMAL, 0.2mg; 0.4mg; 0.6mg (Group I)
3M
Key
Mylan Technologies

NITROGLYCERINE FILM, EXTENDED RELEASE; TRANSDERMAL, 0.2mg; 0.4mg; 0.6mg (Group 2)
Hercon
Mylan Technologies

NITROGLYCERINE FILM, EXTENDED RELEASE; TRANSDERMAL 0.8MG/HR.

NORETHINDRONE TABLET; ORAL 28 (Group 1)
Barr (Camila)
Watson Labs

NORETHINDRONE TABLET; ORAL 28 (Group 2)
- Barr (Errin)
- Ortho McNeil

NORTRIPTYLINE HYDROCHLORIDE, CAPSULE-VARIOUS STRENGTHS
- Mylan
- Sandoz
- Taro
- Teva
- Tyco Healthcare
- Watson

PENICILLIAN G BENZATHINE, INJECTION

PHENDIMETRAZINE TARTRATE, CAPSULE, EXTENDED RELEASE

PHYTONADIONE

POTASSIUM CHLORIDE, CONTROLLED RELEASE, 8MEQ
- Alra
- Copley Pharm
- Novartis
- Upsher Smith

POTASSIUM CHLORIDE TABLET, CONTROLLED RELEASE, 10 mEq
- Andrx
- Apothecon
- Key
- Upsher-Smith (Klor-Con M10 Only)

PREDNISOLONE, TABLET

PREDNISONE TABLET, 5 MG
- Mutual Pharm
- Pharmacia and Upjohn
- PVT Formulations
- Roxane
- Trigen
- Vintage
- Watson
- West-Ward

PROCAINAMIDE HYDROCHLORIDE TABLET, EXTENDED RELEASE, 500 MG
- Copley Pharm
- Pliva
- Sandoz
- Watson

PROCAINAMIDE HYDROCHLORIDE TABLET, EXTENDED RELEASE, 1 GM.

PROMETHAZINE HYDROCHLORIDE, - SUPPOSITORY, RECTAL, 12.5mg; 25mg
Able
Claypark
G and W Labs
Paddock
Wyeth Ayerst

PROMETHAZINE HYDROCHLORIDE, - SUPPOSITORY, RECTAL, 50MG
Able
Wyeth Ayerst

PROMETHAZINE HYDROCHLORIDE, TABLET

PROPANTHELINE BROMIDE TABLET

PROPRANOLOL HYDROCHLORIDE, CAPSULE, EXTENDED RELEASE

PROPYLTHIOURACIL

RESERPINE, TABLET

SILVER SULFADIAZINE CREAM, - TOPICAL
BASF (SSD only)
Kendall LP
King Pharms

SOMATROPIN INJECTION

SOMATROPIN RECOMBINANT INJECTION

SOTALOL HYDROCHLORIDE, TABLET, ALL STRENGTHS (GROUP 1)
Apotex
Berlex (Betapace only)
Eon
GenPharm
Impax
Mutual
Mylan
Teva
Upsher Smith
Vintage
Watson

SOTALOL HYDROCHLORIDE, TABLET, 80MG; 120MG; 160MG (GROUP 2)
Berlex (Betapace AF only)
Mutual Pharm
Torpharm

TECHNETIUM, TC-99M, ALBUMIN AGGREGATED KIT, - INJECTION

TESTOSTERONE FILM, EXTENDED RELEASE; TRANSDERMAL

TESTOSTERONE GEL; TOPICAL

THEOPHYLLINE CAPSULE, CONTROLLED RELEASE
(All strengths are restricted from substitution except for 100 mg; 125 mg; 200 mg; 300 mg with these listed companies)
Aventis (Slo-Bid Only)
Inwood

THEOPHYLLINE TABLET, CONTROLLED RELEASE, 200 MG
Inwood Labs
Pliva

THEOPHYLLINE TABLET, CONTROLLED RELEASE, 300 MG
Inwood Labs
Pliva

THEOPHYLLINE TABLET, CONTROLLED RELEASE, 400 MG

THEOPHYLLINE TABLET, CONTROLLED RELEASE, 600 MG

TRETINOIN GEL; TOPICAL , 0.025%
Johnson and Johnson
Spear

TRETINOIN GEL; TOPICAL, 0.01%
Johnson and Johnson
Spear

TRIAMCINOLONE TABLET

TRICHLORMETHIAZIDE

UROFOLLITROPIN INJECTION, INTRAMUSCULAR; SUBCUTANEOUS

VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE, 180 MG
Abbott
Ivax
Mylan

VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE, 240 MG
Abbott
Ivax
Mylan
Pliva

END.